Remarks:

Claims 1-9 are pending.

The claims are amended, hereby, to resolve issues raised in the rejections under §112, ¶2, as further discussed below, and to, otherwise, more clearly define the invention. For example, present claim 1 (as amended) specifies the "tubular" shape of the "orthosis," inherently recited in original claim 1 (*see* page 1, 1st paragraph, of the specification). Claim 1 is amended, further, by rewriting the "compression simulation means" limitation. More precisely, present claim 1 (as amended) recites

– compression simulation means (48) able to calculate the compression pressure at a plurality of points (68) of said array from data contained in the first and second files by application of Laplaces's law at the plurality of points, as a measure of compression pressure on the limb (30) by the orthosis (70) if applied over the limb.

Support for rewriting the "compression simulation means" feature can be found at page 8, lines 15-30, of the instant specification, which reads:

From data collected and stored in this way, the device then calculates the compression pressure that the orthosis 70 would exert on the leg 30, as modeled, if it were threaded over the latter. This compression pressure is calculated for each section of the leg (associated with a coordinate Z relative to the floor), at the various points of the contour of that section. The theory of calculating the compression pressure at a given point is based on the application of Laplace's law $P = T.c$, where T represents the linear tension of the textile in the circumferential direction and c the curvature of the leg to which the compression is applied.

There has been produced in this way a three dimensional map simulating the compression pressures that the orthosis would apply to the surface of the leg if it were threaded over latter.

Note is taken that Laplace's law is well known in the art, as shown, e.g., by "Theoretical pressures and in vivo pressures: practical consequences of Laplace's law," available online at URL http://dev.urgomedical.com/layout/set/print/content/view/full/470, (copy provided herewith).

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Laplace's law is particularly well known for computing the pressure exerted by an orthosis at a given perimeter of a leg. Note is also taken that "linear tension of the textile in the circumferential direction" is a rheological characteristics contained in the "second file" feature of the present claims; whereas, "curvature of the leg" is a morphological characteristic contained in the "first file" feature of the present claims.

Claims 1-9 were rejected under 35 U.S.C. §112, ¶2, for allegedly being indefinite. Claims 3-9 were rejected under 35 U.S.C. §112, ¶2, for allegedly being indefinite. Claims 4, 6, 8 were rejected under 35 U.S.C. §112, ¶2, for allegedly being indefinite. Claims 8 and 9 were rejected under 35 U.S.C. §112, ¶2, for allegedly being indefinite. Reconsideration of the rejections is requested.

The rejection of claims 1-9 is based on language that does not appear in the rejected claims. According to the rejection (Office Action, page 2):

> Claim 1 recites that the "compression simulation means determines . . . pressure values that are likely to be exerted by the orthosis . . . ". The term "likely to be" is indefinite.

The term "likely to be"—more specifically, the word "likely—does not appear in rejected claim 1 or any other claim. Withdrawal of the objection is, therefore, in order.

Rejection of claims 3-9 under §112, ¶2 is based on alleged inconsistency between "calculated," found in claims 3-9, and "determined," found in claim 1. In accordance with the foregoing amendments, the word "determined" in claim 1 is changed to "calculated," which overcomes the rejection. Withdrawal of the rejection of claims 3-9 under §112, ¶2, is in order..

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The §112, ¶2 of claims 4, 6, and 8 is based on allegedly being no antecedent basis for "the contour of . . . section of a limb." The rejection is overcome in view of the foregoing amendments; whereby, the language allegedly antecedent basis is rewritten "a contour of the cross-section" (claim 6) and "a contour of a cross-section" (claim 8), with antecedent basis for "the cross-section" in claim 6 effected by also amending claim 6 to recite "a cross-section." Withdrawal of the rejection of claims 4, 6, and 8 under §112, ¶2, is in order.

The §112, ¶2, rejection of claims 8 and 9—based on the alleged lack of antecedent basis for reciting "the variation"—is overcome by amending the rejected claims to recite "a variation." Withdrawal of the rejection of claims 8 and 9 under §112, ¶2, is in order.

In view of the foregoing remarks, the rejections of claims 1-9, 3-9, 4, 6, and 8, and 8 and 9 under §112, ¶2, are overcome. Withdrawal of the rejections is in order.

Claims 1-9 were rejected under 35 U.S.C. §103(a) for allegedly being obvious over the teachings of WO 01/11337 as disclosed in US 6,499,356 (Flaud) and further in view of U.S. Pub. No. 2002/0010408 (Pomatto). Reconsideration is requested.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art," *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970), "and it is error to ignore specific limitations distinguishing over the [prior art] reference." *Ex parte Murphy*, 217 USPQ 479, 481 (PO Bd. App.

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1982). A "ground of rejection is simply inadequate on its face...[when] the cited references do not support each limitation of [the] claim." *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002).

In an obviousness analysis, a reference can not be combined with another reference in such a way that destroys the invention on which one of the references is based. *Ex parte Hartmann*, 186 USPQ 366 (POBdApp 1974). When an obviousness rejection combines prior art references in a manner that negates the principle of operation of one of the references, the rejection fails to establish prima facie obviousness. *In re Ratti*, 123 USPQ 349 (CCPA 1959). When a modification of the prior art renders it unsatisfactory for its intended purpose, then there is no motivation for one skilled in the art to make the modification. *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984). *See* MPEP 2143.01.

"One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

> It is impermissible within the framework of §103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.

In re Hedges, 228 USPQ 685, 687 (Fed. Cir. 1986). Teachings of the prior art must be taken as a whole in an obviousness analysis. *Ryko Manufacturing Co. v. Nu-Star, Inc.*, 21 USPQ2d 1053 (Fed. Cir. 1991).

Flaud requires use of an elastic orthosis, i.e., one that exerts compressive force when stretched. On the other hand, Pomatto requires a rigid, inelastic orthosis, which neither stretches nor exerts compressive force.

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The Pomatto orthosis is useful for correcting abnormal cranial shapes in infants. By preventing (i.e., restraining) cranial growth in certain areas, and allowing cranial growth in others, the Pomatto orthosis allows the cranium to grow into a more norman shape.

Accordingly, the Pomatto orthosis can be characterized a *passive* orthosis—exerting no pressure but only resistance to pressure. And, to function as required by Pomatto, i.e., by providing sufficient resistance for the purposes of Pomatto, the Pomatto orthosis must be a rigid and inelastic.

In combining the teachings of Flaud and Pomatto the rejection impermissibly picks and chooses from each of the cited references "only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *Hedges*, 228 USPQ at 687.

On the other hand, taking teachings of the cited Flaud and Pomatto references as a whole, and without the guidance provided by the instant teachings of invention—as required in an analysis under §103(a), *Ryko Manufacturing Co., supra, Fine*, 5 USPQ2d at 1600—shows that one skilled in the art would not have combined the cited references, because to do so would require use of Pomatto's rigid, inelastic orthosis in Flaud—in place of Flaud's elastic orthosis—and, so, destroy the invention on which Flaud is based. *Hartmann, supra, Ratti, supra, Gordon, supra.* As such, the rejection cannot be maintained.

It should also be pointed out that Pomatto—directed solely to the containment action exerted by a rigid orthosis, i.e., a containment action for selectively supporting and immobilizing selected areas of the head of an infant—in no way teaches or suggests an elastic orthosis as presently claimed;

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which, in accordance with the presently claimed invention, exerts when stretched a <u>compressive</u> <u>force</u> on a limb—even when the limb is at rest. The properties exhibited by a claimed invention must be taken into consideration when comparing the claims against the prior art, even when not recited in the claims. *In re Estes*, 164 USPQ 519 (CCPA). *See, In re Papesch*, 137 USPQ 43, 51 (CCPA 1963)..

Besides the fatal deficiencies in the rejection set forth above, there are other fatal flaws in the rejection. According to the statement of rejection (Office Action, page 4), Flaud allegedly meets, inter alia, the claim feature "compression simulation means (48) able to determine, <u>using data from</u> <u>the first</u> and second <u>files</u>, compression pressure values that are liable to be exerted by the orthosis <u>on the limb</u> at a plurality of points of said array." With all due respect, the allegation is poorly taken.

Flaud fails to meet the limitation

> compression simulation means (48) able to determine, using data from the first and second files, compression pressure values that are liable to be exerted by the orthosis on the limb at a plurality of points of said array

recited in the rejected claims, allegations to the contrary in the statement of rejection notwithstanding. First, as acknowledged in the rejection, Flaud neither teaches nor suggests use of the "data from the first...file[]," i.e., as recited in the rejected claims, i.e., the "data" constituted by "a limb . . . in a three-dimensional space" (hereafter, also, referred to as "3-D mapping of the leg"). Flaud discloses only a means for measuring the dimensional and rheological characteristics of the orthosis (i.e. the data stored in the "second file"). Reliance on Pomatto to provide the missing "data" constituted by "a limb . . . in a three-dimensional space" is of no consequence with respect to the

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claim limitation at issue. That is, even assuming arguendo that Pomatto meets the limitation to "data" constituted by "a limb ... in a three-dimensional space," the rejection still fails to show how "using" the "data from the first...file[]"—to which the rejected (and present) claims are limited—is met by the cited references.

There is no teaching or suggestion in Flaud to use a 3-D "mapping" of the leg, let alone to bring it together with the dimensional and rheological characteristics of the elastic orthosis, which constitute "the data from the...second file[]," in order to compute therapeutic compression values at a multiplicity of points of the 3-D mapping of the leg, as presently claimed.

Pomatto provides no teaching or suggestion that cures the fatal flaw in Flaud (explained above). Pomatto neither teaches nor suggests combining "data from the first and second files," as presently claimed.

Accordingly, the teaches of Flaud and Pomatto, taken alone or together, fail to support the limitation of the rejected claims (emphasis added) to "using" the "data from the first and second files." Since "the cited references do not support each limitation of [the] claim[s]," the rejection is "inadequate on its face." *Thrift*, 63 USPQ2d at 2008.

Second, when Flaud refers to a "pressure" that is measured or displayed (col. 4, 1.6-8; col. 5, 1.9-13 of Flaud), Flaud means the pressure exerted by the orthosis ("the hose") on the jig 14, specifically at every location of a sensor 40 (the sensor measures the force exerted locally by the hose, hence giving the pressure after a division by the ares of the sensor).

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Pressure exerted by an orthosis—as taught by Flaud—on a jig is quite different from (i.e., does not meet) the pressure that would be exerted by an orthosis on a leg after the orthosis is put on that leg, since the pressure exerted by the latter (i.e., the therapeutic compression pressure) would depend on the local curvature of the leg, as given by Laplace's law (explained above).

Although (as explained above) the combined teachings of Flaud and Pomatto fail to teach (or suggest) the "compression jig ......